JUL 13 2007

Section 13: 510(k) Summary

K071354

510(k) SUMMARY

Applicant:	Mölnlycke Health Care 5550 Peachtree Parkway Suite 500 Norcross, GA 30092	
Contact Person:	Steven Dowdley Director of Regulatory Affairs Tel.: 678-250-7930 Fax: 678-250-7981	
Device Name:	Proprietary Name: Common/Usual Name: Device Classification:	Mepilex Ag Dressing Silver Dressing Unclassified
Predicate Device	Mepilex Ag Dressing	

Description:
Mepilex Ag is an anti-microbial, absorbent soft silicone dressing consisting of a flexible, absorbent polyurethane foam pad with added silver and activated charcoal, which is coated with a silicone wound contact layer and a wrinkled water vapor permeable polyurethane film backing. The silicone layer is covered with a polyethylene release film.

Intended Use:
Mepilex Ag Dressing is indicated for the management of low to moderately exuding wounds such as leg and foot ulcers, pressure ulcers and partial thickness burns. Silver sulphate present in the dressing helps reduce microbial colonization on the dressing.

Substantial Equivalence

- Comparison of Technological Characteristics – No changes have been made to the currently marketed device or device indication for use.
- Non-clinical Data - The data provided in this submission substantiate a 24 month shelf life. No additional studies were performed.
- Clinical Data - Not applicable

Conclusion:
The date provided in this 510(k) summary concludes that Mepilex Ag Absorbent Silicone-Coated Dressing is substantially equivalent to the currently marketed Mepilex Ag Absorbent Silicone-Coated Dressing marketed under K061554.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Molnlycke Heath Care Inc.
% Mr. Steven Dowdley, RAC
Director, Regulatory Affairs
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K071354
Trade/Device Name: Mepilex Ag Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 10, 2007
Received: May 15, 2007

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071354

Device Name: Mepilex Ag Dressing

Indications For Use:

Mepilex Ag Dressing is indicated for the management of low to moderately exuding wounds such as leg and foot ulcers, pressure ulcers and partial thickness burns. Silver sulphate present in the dressing helps reduce microbial colonization on the dressing.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071354